APPLICATION

FOR

UNITED STATES LETTERS PATENT

PATENT APPLICATION

SPECIFICATION

TO ALL WHOM IT MAY CONCERN:

Be it known that Frederic P. Field of 5 Woodland Road, North Hampton, NH 03862 and Gregory E. Sancoff of 120 Mill Road, North Hampton, NH 03862, have invented certain improvements in SURGICAL INSTRUMENT AND METHOD OF USE, of which the following description is a specification.

PS/ONUX19.CVR

SURGICAL SUTURING INSTRUMENT AND METHOD OF USE

Reference To Pending Prior Patent Application

This is a continuation-in-part of pending prior U.S. Patent Application Serial No. 09/818,300, filed 03/27/01 by Gregory E. Sancoff et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE, which is a continuation-in-part of pending prior U.S. Patent Application Serial No. 09/368,273, filed 08/03/99 by Gregory E. Sancoff et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE.

And this patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/242,237, filed 10/20/00 by Frederic P. Field et al. for SURGICAL SUTURING INSTRUMENT AND METHOD OF USE (Attorney's Docket No. ONUX-16 PROV), which patent application is hereby incorporated herein by reference.

Field Of The Invention

This invention relates to medical suturing instruments and more particularly to drive means in

such instruments for advancing a suture strand through tissue, and the like.

Background Of The Invention

Suturing instruments are typically used to draw together two or more portions of a subject patient (e.g., tissue such as muscle or skin) or to attach an object to the patient (e.g., to attach a piece of surgical mesh to the abdominal wall of the patient during hernia repair surgery).

Certain suturing instruments employ a needle that precedes a length of suture material through a subject.

For example, U.S. Patents Nos. 3,470,875; 4,027,608; 4,747,358; 5,308,353; 5,674,230; 5,690,653; 5,759,188; and 5,766,186 generally disclose suturing instruments in which a needle, with trailing suture material, is passed through a subject.

U.S. Patents Nos. 4,890,615; 4,935,027; 5,417,700; and 5,728,112 generally disclose suturing instruments in which suture material is passed through the end of a hollow needle after that needle has passed through a subject.

With all of the foregoing devices, a needle must be passed through the subject in order to deploy the suture. This is generally undesirable, since the needle typically leaves a larger hole in the subject than is necessary to accommodate only the suture material. In this respect it should be appreciated that it is generally desirable to alter each portion of the material being sutured as little as possible.

A suturing instrument has been devised which permits the suture material itself to pierce the subject without the use of a needle. However, this device does not permit sufficient flexibility with regard to the amount of tension that may be applied to the suture and tissue.

More particularly, U.S. Patent No. 5,499,990 discloses a suturing instrument in which a 0.25 mm stainless steel suturing wire is advanced to the distal end of a suturing instrument, whereupon the distal end of the suturing wire is caused to travel in a spiral direction so as to effect stitches joining together two portions of a subject. After the spiral is formed, the beginning and end portions of the suture may be bent

toward the tissue in order to inhibit retraction of the suture wire into the tissue upon removal of the suturing instrument. The stainless steel wire is sufficiently firm to hold this locking set. In addition, after the spiral is formed, the radius of the deployed suture spiral may then be decreased by advancing an outer tube over a portion of the distal end of the instrument. Again, the stainless steel wire is sufficiently firm to hold this reducing set.

Unfortunately, however, such a system does not permit sufficient flexibility in all situations with regard to the appropriate amount of tension to be applied to the subject, since the wire is relatively firm (i.e., firm enough to hold its sets). Such a system also does not provide sufficient flexibility with regard to the appropriate type of suture stitch to be applied, since the device is specifically configured to provide only a spiral suture stitch.

In contrast to the aforementioned limitations of the suturing instrument of U.S. Patent No. 5,499,990, it is desirable that a suturing instrument approximate the portions of the material which is to be joined in

the correct physiological relationship, and to urge the portions together with an appropriate amount of force. If too much force (or tension) is applied to the suture material, then the subject portions may become necrotic or the sutures may cut through the subject. If too little tension is applied to the suture material, then the healing process may be impaired.

U.S. Patent No. 4,453,661 discloses a surgical instrument for applying staples. The staples are formed from the distal end of a length of wire. The distal end of the wire is passed through a subject, and thereafter contacts a die that causes the wire to bend, thereby forming the staple. The wire is sufficiently firm to take the set imposed by the die. The staple portion is then cut from the wire by a knife. Again, such a system suffers from the fact that it does not permit sufficient flexibility in all situations with regard to the appropriate tension to be applied to the subject, since the attachment is made by a staple which has a predefined geometry and is formed with relatively firm wire. In addition, the system is limited as to the type of fastening which may be applied, since the

surgical instrument is limited to only applying wire staples.

There is a need, therefore, for a new suturing device that permits minimally disruptive suturing and permits flexibility in the placement, application, and tensioning of the suture material.

Summary Of The Invention

The invention provides a device for introducing a flexible elongated element through a subject.

In one form of the invention, the device includes a tool for joining a first layer of material to a second layer of material, the tool comprising a handle, a first jaw and a second jaw mounted on the handle, at least one of the first jaw and the second jaw being moveable relative to the other; the first jaw defining therein: a first channel for retaining a wire guide; a second channel extending from the first channel for supporting a suture wire extending from the wire guide; and a passageway for retaining a cutting bar; the second channel being curved to impart a looping configuration to portions of the suture wire passed

therethrough; a wire advancing actuator mounted on the handle for moving the suture wire through the second channel and through the first and second layers of material in the looping configuration; and a wire cutting actuator mounted on the handle for moving the cutting bar into cutting engagement with the suture wire, wherein the suture wire in the looping configuration joins the first layer of material to the second layer of material.

In another form of the invention, there is provided a method for joining a first layer of material and a second layer of material, the method comprising:

providing a tool for joining a first layer of material to a second layer of material, the tool comprising:

a handle;

a first jaw and a second jaw mounted on the handle, at least one of the first jaw and the second jaw being moveable relative to the other;

the first jaw defining therein:

a first channel for retaining a wire guide;

a second channel extending from the first channel for supporting a suture wire extending from the wire guide; and

a passageway for retaining a cutting bar;

the second channel being curved to impart a looping configuration to portions of the suture wire passed therethrough;

a wire advancing actuator mounted on the handle for moving the suture wire through the second channel and through the first and second layers of material in the looping configuration; and

a wire cutting actuator mounted on the handle for moving the cutting bar into cutting engagement with the suture wire, wherein the suture wire in the looping configuration joins the first layer of material to the second layer of material;

placing the first layer of material and the second layer of material between the first jaw and the second jaw;

advancing the suture wire out of the first jaw to form the looping configuration of the suture wire

through the first layer of material and the second layer of material between the first jaw and the second jaw so as to join the first layer and the second layer to one another;

advancing the cutting bar through the suture wire so as to sever the looping configuration of the suture wire and a remaining portion of the suture wire in the second channel from one another.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description of the preferred embodiment of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like parts, and further wherein:

Fig. 1 is a side view of a suturing instrument formed in accordance with the present invention;

Fig. 2 is a partial side view, partially in section, of the suturing instrument shown in Fig. 1;

Fig. 3 is a partial top view, partially in section, of the suturing instrument shown in Fig. 1;

Fig. 4 is a schematic partial side view showing some of the internal components of the suturing instrument shown in Fig. 1;

Fig. 4A is a perspective view of a drive barrel assembly incorporated in the suturing instrument shown in Fig. 1;

Fig. 5 is a perspective view of a wire guide support unit incorporated in the suturing instrument shown in Fig. 1;

Fig. 6 is a perspective view of the suturing instrument's wire supply cartridge, which includes the wire guide support unit shown in Fig. 5;

Fig. 7 is a perspective view, partially in section, of the wire supply cartridge shown in Fig. 6;

Fig. 8 is a perspective rear view of the drive barrel assembly incorporated in the suturing instrument shown in Fig. 1, with the drive barrel assembly's release lever being shown in its closed position;

Fig. 9 is a perspective view of the proximal (i.e., rear) end of the drive barrel assembly shown in

Fig. 8, with the release lever being shown in its open position;

Fig. 10 is a perspective view of the proximal (i.e., rear) end of the same drive barrel assembly, with the release lever being shown in its closed position, and with the wire guide and wire guide support unit being advanced relative to the drive barrel assembly (but with the remainder of the wire supply cartridge being removed from view);

Fig. 11 is a schematic view taken along the line 11-11 of Fig. 4;

Fig. 12 is a side view of a shaft and an end effector portion of the suturing instrument shown in Fig. 1;

Fig. 13 is a side view of the end effector portion of the suturing instrument shown in Fig. 1;

Fig. 14 is a side view, partially in section, of the end effector portion shown in Fig. 13, with the end effector portion being shown with its cutting bar in its forward (i.e., non-cutting) position;

Fig. 15 is a side view, partially in section, of the end effector portion shown in Fig. 14, but with the

end effector portion being shown with its cutting bar in its retracted (i.e., cutting) position;

Fig. 16 is a perspective view of the end effector portion of the suturing instrument shown in Fig. 1;

Figs. 17A - 17J show various steps in a suturing operation conducted with the suturing instrument shown in Fig. 1;

Fig. 18 is a sectional view showing one possible construction for the suturing instrument's fixed jaw portion and its associated cutting bar;

Fig. 19 is a side view showing a piece of wire cut with the apparatus shown in Fig. 18;

Fig. 20 is a sectional view showing another possible fixed construction for the suturing instrument's fixed jaw portion and its associated cutting bar;

Fig. 21 is a side view showing a piece of wire cut with the apparatus shown in Fig. 20;

Fig. 22 is a side view, partially in section, of the end effector portion of the device, wherein the end effector portion includes a piezoelectric element to aid in wire penetration;

Fig. 23A is a schematic diagram of the device's fixed jaw portion, illustrating how the suture wire may sometimes curve as it exits the fixed jaw portion;

Fig. 23B is a schematic diagram of a modified form of the device's fixed jaw portion, illustrating how the profile of the device can be modified so as to counteract the aforementioned wire curvature;

Fig. 23C is a schematic diagram of a modified form of the device's movable jaw portion, illustrating how the mouth of the movable jaw portion's opening may be enlarged so as to facilitate suture capture;

Fig. 24 is a schematic diagram of a modified form of the device, wherein one or more legs have been provided to help stabilize the tissue during suturing;

Fig. 25 is a schematic diagram of another modified form of the device, wherein a second set of jaws have been added to the device to help stabilize the tissue during suturing;

Fig. 26 is a perspective view of a portion of an alternative end effector portion of the instrument;

Fig. 27 is a perspective view of a further portion of the alternative end effector portion;

Fig. 28 is a perspective view of the alternative end effector, including the portions of Figs. 26 and 27;

Fig. 29 is a diagrammatic illustration of the alternative end effector in operation;

Figs. 30-33 are diagrammatic illustrations of alternative modes of suturing accomplished with the alternative end effector;

Fig. 34 is a diagrammatic side elevational view, broken away, showing an alternative use of a looped suture wire produced by the alternative effector portion of the instrument;

Fig. 35 is a perspective view of an end portion of another alternative embodiment of end effector; and

Fig. 36 is a perspective view of another alternative embodiment of end effector portion of the instrument.

Fig. 37 is a side elevational view of still another alternative embodiment of instrument;

Fig. 38 is a perspective view of an alternative configuration of end effector;

Figs. 39-41 are perspective views of still another alternative embodiment of end effector;

Figs. 42a-42c are diagrammatic illustrations of suturing by use of an alternative end effector;

Fig. 43 is an exploded view of still another alternative embodiment of end effector;

Fig. 44 is a side view of a portion of an alternative end effector portion of the instrument;

Fig. 45 is a schematic top perspective view of the alternative end effector shown in Fig. 44;

Fig. 46 is a schematic bottom perspective view of the alternative end effector shown in Fig. 44;

Fig. 47 is another side view of the end effector shown in Fig. 44; and

Fig. 48 is still another side view of the end effector shown in Fig. 44.

Detailed Description Of The Preferred Embodiment

Overview

Looking first at Fig. 1, there is shown a suturing instrument 10 which comprises a preferred embodiment of

the present invention. Suturing instrument 10 includes a housing 12, a handle 14, a shaft 16 and an end effector 18. Suturing instrument 10 also includes a wire advance button 20, a jaw closing actuator 22, a wire cutting actuator 24, a left-thumb-actuated rotation button 26, and a right-thumb-actuated rotation button 28 (Fig. 3). Suturing instrument 10 also includes a wire supply cartridge 30, as well as a shaft retaining nut 32. Shaft retaining nut 32 allows shaft 16 to be dismounted from the remainder of the device for cleaning purposes.

As will be discussed in further detail below, generally during use, suture wire (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) is drawn from a winding in wire supply cartridge 30 and is pushed through housing 12 and shaft 16 to end effector 18, which includes a pair of opposing jaw portions. The jaw portions may be brought together around the material which is to be sutured by actuating jaw closing actuator 22 when the jaw portions are positioned at an appropriate surgical location. The

suture wire is driven through housing 12 and shaft 16 to end effector 18 by actuating wire advance button 20. The suture wire is driven from one jaw portion to the other jaw portion with sufficient force to penetrate the tissue placed between the jaw portions, and the suture wire is permitted to pass through the second jaw portion. The jaw portions are then permitted to separate and move away from the tissue, leaving the suture wire extending from the subject tissue to each of the two jaw portions. Shaft 16 and end effector 18 (together with wire supply cartridge 30) may then be rotated with respect to housing 12 and handle 14 by actuating either left-thumb-actuated rotation button 26 or right-thumb-actuated rotation button 28. This causes the portions of the suture wire that extend from the tissue to be twisted about one another so as to form a closed loop extending through the tissue. It will be appreciated that the size of this closed loop may be adjustably reduced by increasing the degree of twisting in the wire. The twisted loop of suture wire may then be cut off, at end effector 18, from the remaining portion of the suture wire that extends back

through the suturing instrument. Such cutting may be effected by actuating wire cutting actuator 24.

As will be discussed in further detail below, wire supply cartridge 30 may be supplied separately from suturing instrument 10, with the wire supply cartridge 30 being loaded into suturing instrument 10 prior to commencing a suturing operation. As will also be discussed in further detail below, wire supply cartridge 30 may be disposable, such that the cartridge may be discarded after all of its wire has been used up.

Construction Details

As shown in Figs. 2 and 4, handle 14 provides a cavity that may receive batteries 34. In other embodiments, the unit may be powered remotely via a power transmission cord or any other source of suitable power.

Batteries 34 supply a ground (or negative) potential to a ground connector post 36 (Fig. 2), which in turn communicates with a rotary ground communicator 38. Rotary ground communicator 38 permits electrical contact to be maintained with ground connector post 36

when rotary ground communicator 38 is rotated with respect to ground connector post 36, as occurs when shaft 16 and end effector 18 are rotated so as to twist closed suture wire extending through the tissue.

Batteries 34 supply a positive potential to wire advance button 20, and to a first connector post 40, which in turn communicates with a first rotary electrical communicator 42. First rotary electrical communicator 42 permits electrical contact to be maintained with first connector post 40 when first rotary electrical communicator 42 is rotated with respect to first connector post 40. The positive potential from batteries 34 is also supplied (in parallel) to each thumb-activated rotation button 26, 28 (Fig. 3), and to a second connector post 44 (Fig. 2), which in turn communicates with a second rotary electrical communicator 46. Again, second rotary electrical communicator 46 permits electrical contact to be maintained with second connector post 44 when second rotary electrical communicator 46 is rotated with respect to second connector post 44. Each of the connector posts 36, 40 and 44 may be

spring-biased so as to remain in contact with its respective rotary communicator. In view of the foregoing construction, the positive potentials may be switched on by depressing the respective actuator button 20, 26, 28. Handle 14 also includes a cap 48 which may be removed so as to permit insertion of batteries 34.

First rotary electrical communicator 42 is in electrical communication with a wire advance motor 50 shown in Figs. 2 and 4. The output shaft of wire advance motor 50 is coupled to a miter drive gear 52, which is in turn coupled to a miter follower gear 54. Miter follower gear 54 is coupled to a drive wheel 56 which contacts a suture wire 58, as will be described in further detail below with reference to Figs. 5-10.

Second rotary electrical communicator 46 is in electrical communication with a shaft rotation motor 60 (Figs. 3 and 4), the output of which is coupled to a pinion gear 62 (Figs. 4, 4A and 11) that rotates along an internal gear 64 (Figs. 4 and 11). As shown in Fig. 3, left-thumb-actuated rotation button 26 and

right-thumb-activated rotation button 28 may be provided to permit the user to use the thumb of either their left hand or their right hand, respectively, so as to actuate shaft rotation motor 60. In this respect it will be appreciated that, inasmuch as left-thumb-actuated rotation button 26 and right-thumb-actuated rotation button 28 are wired in parallel, shaft rotation motor 60 will rotate in the same direction regardless of which button (i.e., button 26 or button 28) may be actuated.

Jaw closing actuator 22 (Figs. 2 and 4) is coupled to a jaw linkage coupler 66, which in turn contacts a jaw linkage 68 (Figs. 2 and 14). When jaw closing actuator 22 is pulled toward handle 14 (Fig. 2), jaw closing actuator 22 pivots on its pivot pin 67 (Fig. 4) so as to drive jaw linkage coupler 66 distally, against the force of biasing spring 69, and so as to cause the jaw linkage 68 to move forward toward the distal end of suturing instrument 10. This action will in turn cause a movable jaw portion 98 to close on a fixed jaw portion 96 (Fig. 17A), as will hereinafter be discussed in further detail. When jaw closing actuator 22 is

subsequently released, biasing spring 69 (Fig. 4) drives jaw linkage coupler 66 proximally, so as to cause jaw linkage 68 to move proximally. This action will cause movable jaw portion 98 to open relative to fixed jaw portion 96 (Fig. 14), as will hereinafter be discussed in further detail. The action of jaw linkage 68 at the distal end of the device is discussed further below with reference to Figs. 13 and 14.

Wire cutting actuator 24 is coupled to a wire cutting linkage coupler 70 (Figs. 2 and 4), which in turn contacts a wire cutting linkage 72 (Figs. 2, 14 and 15). When wire cutting actuator 24 is pulled toward handle 14 (Fig. 2), wire cutting actuator 24 pivots on its pivot pin 73 (Fig. 4) so as to drive wire cutting linkage coupler 70 proximally, against the force of biasing spring 69, and so as to cause wire cutting linkage 72 to move proximally, away from the distal end of suturing instrument 10. This action will in turn cause cutting bar 104 (Fig. 14) to move proximally (Fig. 15) so as to effect wire cutting, as will hereinafter be discussed in further detail. When wire cutting actuator 24 is subsequently released,

biasing spring 69 drives wire cutting linkage coupler 70 distally, so as to cause wire cutting linkage 72 to move distally. This action causes a cutting bar 104 to move distally, so as to assume the position shown in Fig. 14. Wire cutting linkage 72 moves adjacent to, and independent of, jaw linkage 68 discussed above. The action of wire cutting linkage 72 at the distal end of the device is discussed further below with reference to Figs. 14 and 15.

The wire supply cartridge 30 shown in Fig. 1 includes a wire guide support unit 74, as shown in Figs. 5-7. A supply coil of suture wire 58 (comprising wire formed of metal or any other suitable material having the required flexibility and stiffness) may be supplied in the base of cartridge 30 and is fed into the support unit 74 as shown in Fig. 7. A wire guide 76 surrounds suture wire 58, from support unit 74 to the distal end of suturing instrument 10, adjacent to end effector 18 (Figs. 5-7, 14 and 15). Wire guide 76 ensures that suture wire 58 does not bend or buckle as the suture wire is pushed through housing 12 and shaft 16. More particularly, wire guide 76 preferably forms

a sufficiently close sliding fit with suture wire 58 such that suture wire 58 cannot bend or buckle as the suture wire is advanced through suturing instrument 10. At the same time, wire guide 76 is also formed so as to present a minimum of friction to suture wire 58 as the suture wire is advanced through the instrument. The foregoing characteristics are important, inasmuch as suture wire 58 is extremely thin and flexible and highly susceptible to bending or buckling in the absence of some sort of lateral support.

By way of example but not limitation, where suture wire 58 is formed out of stainless steel and has a diameter of 0.005 inch, wire guide 76 might have an inside diameter of 0.008 inch and an outside diameter of 0.016 inch. In addition, wire guide 76 is preferably formed out of polytetrafluoroethylene (PTFE) or some other relatively lubricious material. Alternatively, the interior of wire guide 76 may be coated with a lubricant so as to facilitate closely-supported, low-friction passage of the suture wire through the wire guide.

Further by way of example but not limitation, in one preferred form of the invention, suture wire 58 may comprise 316 LVM stainless steel having a tensile strength of 170 kpsi.

Although wire guide 76 extends through support unit 74 (Fig. 7), wire guide 76 has two openings 78 (one on either side of wire guide 76, only one of which is shown in Fig. 5) in the center of support unit 74. Openings 78 expose a portion of suture wire 58 so that wire drive wheel 56 (Fig. 8) may contact suture wire 58 and urge the suture wire forward toward the distal end of suturing instrument 10, as will be discussed in detail below with reference to Figs. 8-10.

As shown in Figs. 2, 3, 4A and 8, housing 12 receives a drive barrel assembly 80 that contains the aforementioned motors 50 and 60, and provides a distally-extending barrel shaft 81 (Figs. 4A and 8), on the outside of which are located the rotary communicators 38, 42 and 46. A recess 82 (Fig. 4A) is provided on the distal end of barrel shaft 81 for receiving a coupling pin 84 (Figs. 2 and 4) which is located on the proximal end of shaft 16, such that

rotation of drive barrel assembly 80 causes rotation of coupling pin 84 and hence shaft 16. Drive barrel assembly 80 is rotationally held within housing 12 by bearings 86, as shown in Figs. 2 and 3.

Looking next at Figs. 7-10, wire supply cartridge 30 may be attached to drive barrel assembly 80 by rotating a release lever 87 away from the center of drive barrel assembly 80 (Figs. 8 and 9), so as to move a carriage 88 relative to drive barrel assembly 80. Most particularly, release lever 87 rides on a pin 90, and rotation of release lever 87 from the position shown in Fig. 8 to the position shown in Fig. 9 draws carriage 88, as well as a wire follower wheel 92, away from the center of drive barrel assembly 80. Once wire follower wheel 92 is separated from wire drive wheel 56 by a sufficient distance to expose the drive barrel assembly's central passageway 93 (Fig. 9), wire guide 76 (overlying suture wire 58) may be inserted into passageway 93 (Fig. 10), and wire guide support unit 74 (Figs. 6, 7 and 10) may be inserted between wheels 56 and 92 (Fig. 10), such that wheels 56 and 92 contact either side of suture wire 58 through openings 78

formed in either side of wire guide 76. A biasing spring 94 (Figs. 8-10) is provided on carriage 88 to urge wire follower wheel 92 into close contact with suture wire 58. In other embodiments, wire follower wheel 92 may also be driven indirectly by wire drive wheel 56 in order to provide additional forces to move suture wire 58 distally (i.e., forward, toward the tool's end effector 18).

Pinion gear 62 (Figs. 4, 4A and 11) extends distally from drive barrel assembly 80 and engages the housing's internal gear 64, as shown in Figs. 4 and 11. As a result of this construction, when shaft rotation motor 60 is actuated, pinion gear 62 rotates around internal gear 64, bringing with it the entire drive barrel assembly 80. This in turn causes shaft 16 to rotate, since shaft 16 is coupled to drive barrel assembly 80. More particularly, the rotation of drive barrel assembly 80 is transferred to shaft 16 through the shaft's coupling pin 84 (Figs. 2, 4 and 12), which is seated in recess 82 (Fig. 8) of drive barrel assembly 80.

End effector 18 (Figs. 1 and 13-16) includes the fixed jaw portion 96 and the movable jaw portion 98. Movable jaw portion 98 is coupled to the aforementioned jaw linkage 68 (Fig. 14) via a jaw linkage pin 100, such that when jaw linkage 68 is moved distally (i.e., by pulling jaw closing actuator 22 toward handle 14), jaw portion 98 is rotated about a pivot pin 102 (Fig. 13) and closes onto fixed jaw portion 96. Conversely, when jaw linkage 68 is moved proximally (i.e., by the power of biasing spring 69 acting on jaw linkage coupler 66 and hence jaw linkage 68), movable jaw portion 98 will open away from fixed jaw portion 96. It will be appreciated that the force of biasing spring 69 will normally keep movable jaw portion 98 open relative to fixed jaw portion 98 (Figs. 1, 13 and 14), unless and until jaw closing actuator 22 is activated so as to overcome the bias of spring 69.

Wire cutting linkage 72 (Figs. 2, 3, 14 and 15) is coupled to cutting bar 104 (Figs. 14 and 15) that includes a small opening 106 through which suture wire 58 may pass, as will hereinafter be discussed in further detail. Preferably cutting bar 104 is slidably

received in a passageway 107 (Figs. 14, 15, 16 and 17H) formed in fixed jaw portion 96. In one position (Fig. 14), cutting bar 104 is positioned in fixed jaw portion 96 such that the cutting bar's opening 106 is aligned with a channel 108 formed in fixed jaw portion 96, whereby suture wire may be passed from the distal end of wire guide 76, through channel 108 formed in fixed jaw portion 96 (where it undergoes an approximately 90 degree change of direction), through opening 106 in cutting bar 104, through a channel extension 108A formed in fixed jaw portion 96, and across to movable jaw portion 98, as will hereinafter be discussed in further detail. However, when wire cutting linkage 72 is moved proximally by pulling wire cutting actuator 24 toward handle 14, cutting bar 104 is also moved proximally (Fig. 15) so as to cut any suture wire extending from channel 108 (in fixed portion 96) into opening 106 (in cutting bar 104). In this respect it will be appreciated that it is desirable to form channel extension 108A with a length greater than channel 108 (see Figs. 14 and 15) so as to prevent the suture wire from being cut in two places (i.e., at

channel 108 and again at channel extension 108A) when cutting bar 104 is moved proximally by pulling on wire cutting actuator 24. At the same time, however, it should also be appreciated that the fixed jaw portion's channel 108 and channel extension 108A, and the cutting bar's opening 106, are all sized, relative to suture wire 58, so as to provide as much support as possible to the suture wire as it passes through, and out of, fixed jaw portion 96.

It will be appreciated that the force of biasing spring 69 will normally keep cutting bar 104 in its distal position (i.e., with the cutting bar's opening 106 aligned with the fixed jaw portion's channel 108), unless and until wire cutting actuator 24 is activated so as to overcome the bias of spring 69.

In view of the foregoing construction, it will be seen that: (1) release lever 87 (Figs. 8-10) may be activated so as to move wire follower wheel 92 away from, and toward, wire drive wheel 56 so as to permit a full wire supply cartridge 30 (Figs. 1 and 5-7) to be loaded into suturing instrument 10; (2) activating jaw closing actuator 22 will cause movable jaw portion 98

to close on fixed jaw portion 96; (3) activating wire advance button 20 will cause wire drive wheel 56 to advance suture wire 58 through housing 12 and shaft 16; (4) activating rotation button 26 and/or rotation button 28 will cause shaft 16 to rotate relative to housing 12; and (5) activating wire cutting actuator 24 will cause cutting bar 104 to move proximally so as to sever any suture wire extending from fixed jaw portion 96.

Operation

Suturing instrument 10 may be used to apply wire suture 58 to a subject so as to effect a desired suturing operation.

By way of example but not limitation, and looking now at Figs. 17A-17J, suturing instrument 10 may be used to suture together two portions 110, 112 of a subject which is to be sutured. In a typical case, portions 110, 112 might comprise two sections of severed tissue which need to be reattached to one another, or two pieces of previously unattached tissue which need to be attached to one another. However, one

or the other of the portions 110, 112 might also comprise artificial mesh or some other object being attached to tissue, etc. In addition, in a typical case, portions 110, 112 might be located relatively deep within a patient, and might be accessed during a so-called "minimally invasive", or a so-called "closed surgery", procedure; however, in other circumstances, portions 110, 112 might be accessed during a conventional, or so-called "open surgery", procedure. This later situation might include procedures done at the outer surface of the patient's body, i.e., where portions 110, 112 comprise surface subjects.

In any case, suturing instrument 10 is initially prepared for use by installing batteries 34 into handle 14, if batteries 34 are not already installed, and by installing wire supply cartridge 30 into the suturing instrument, if a cartridge 30 is not yet installed. As noted above, wire supply cartridge 30 is installed in suturing instrument 10 by (1) moving the drive barrel assembly's release lever 87 to its open position (Fig. 9), so as to move wire follower wheel 92 away from wire drive wheel 56 and thereby expose the barrel assembly's

central passageway 93; (2) passing the distal end of the cartridge (i.e., the distal end of wire guide 76) through drive barrel assembly 80 and shaft 16 until the distal end of wire guide 76 is in communication with the channel 108 formed in fixed jaw portion 96 (Fig. 14), at which point the cartridge's wire guide support unit 74 will be positioned intermediate wire drive wheel 56 and wire follower wheel 92 (Fig. 2); and (3) moving the drive barrel assembly's release lever 87 back to its closed position (Fig. 8), so as to cause wire drive wheel 56 and wire follower wheel 92 to extend through the wire guide's openings 78 and engage suture wire 58.

At this point suturing instrument 10 will be ready for use, with its movable jaw portion 98 being opened away from its fixed jaw portion 96, and with its cutting bar 104 being in its forward (Fig. 14) position.

Next, suturing instrument 10 has its movable jaw portion 98 moved into engagement with its fixed jaw portion 96 (i.e., the jaws 96, 98 are placed in their "closed" position) by pulling jaw closing actuator 22

toward handle 14, and then the distal end of suturing instrument 10 is moved adjacent to subject portions 110, 112 (Fig. 17A).

In the case of a so-called closed surgical procedure, such positioning will generally involve moving the distal end of the suturing instrument through a cannula and into an interior body cavity; however, it is also envisioned that one might move the distal end of the suturing instrument directly into an otherwise-accessible body cavity, e.g., directly into the colon or esophagus, etc. In the case of a so-called open surgical procedure, such positioning might involve positioning the distal end of the suturing instrument adjacent to more readily accessible subject portions 110, 112.

In any case, once the distal end of suturing instrument 10 has been placed adjacent to subject portions 110, 112, jaw closing actuator 22 is released, such that biasing spring 69 (Fig. 4) will cause movable jaw portion 98 to open away from fixed jaw portion 96 (Fig. 17B). Then the distal end of suturing instrument 10 is moved so that its jaws 96, 98 straddle subject

portions 110, 112, and then jaw closing actuator 22 is actuated again, by pulling jaw closing actuator 22 toward handle 14, so as to close movable jaw portion 98 against fixed jaw portion 96, whereby to capture subject portions 110, 112 (Fig. 17C).

Next, wire advance button 20 is activated so as to cause suture wire 58 to be driven forward, out of the distal end of wire guide 76, through the fixed jaw portion's channel 108, through opening 106 in cutting bar 104, through the fixed jaw portion's channel extension 108A, through subject portions 110, 112, and finally through an opening 113 (Figs. 14, 15 and 17C) formed in movable jaw portion 98. Suture wire 58 is preferably advanced so that a length 58A of wire 58 extends approximately 1 centimeter out of the bottom end of movable jaw portion 98 (Fig. 17C). In this respect it will be appreciated that, as suture wire 58 leaves fixed jaw portion 96 and engages subject portions 110, 112, the fixed jaw portion's channel 108, the cutting bar's opening 106 and the fixed jaw portion's channel extension 108A will support the thin

suture wire so as to enable the suture wire to penetrate subject portions 110, 112.

Once this has been done, jaw closing actuator 22 is released so as to permit movable jaw portion 98 to return to its "open" position relative to fixed jaw portion 96, and then wire advance button 20 is used to pay out additional suture wire 58 as the distal end of suturing instrument 10 is stepped back (e.g., by about a centimeter or so) from subject portions 110, 112 (Fig. 17D).

Then jaw closing actuator 22 is used to move jaw portion 98 back into engagement with fixed jaw portion 96 once more (Fig. 17E).

Next, left-thumb-actuated rotation button 26, or right-thumb-actuated rotation button 28, is used to rotate shaft 16 and hence end effector 18. This causes suture wire 58 to twist on itself, initially creating a relatively large loop 116 (Fig. 17F) of suture wire 58 extending from subject portions 110, 112 toward suturing instrument 10. However, as rotation button 26 and/or rotation button 28 is used to rotate shaft 16 (and hence end effector 18) more and more, the loop 116

of suture material will progressively close down (Fig. 17G) so as to form a tight binder for subject portions 110, 112. In this respect it will be appreciated that the longer the period of time that end effector 18 is rotated, the greater the amount of twisting of suture wire 58, and the greater the force holding subject portions 110, 112. In this respect it will also be appreciated that suture wire 58 is preferably carefully selected with respect to its flexibility relative to the strength of subject portions 110, 112. In particular, suture wire 58 is chosen so as to have a flexibility such that the suture wire will twist, and loop 116 will close down, before subject portions 110, 112 will undergo substantial deformation and/or tearing. By way of example but not limitation, in practice, it has been found that 0.005 inch diameter stainless steel wire can be used with most types of mammalian tissue such that the suture wire can be twisted closed without causing substantial deformation and/or tearing of the tissue.

Once suture wire 58 has been tightened to the desired degree, rotation of shaft 16 and end effector

18 is stopped, i.e., by releasing button 26 or button 28. Then wire cutting actuator 24 is depressed (e.g., it is pulled back toward handle 14) so as to pull cutting bar 104 proximally and thereby sever the suture wire 58 as the suture wire emerges from the fixed jaw portion's channel 108 and enters the cutting bar's opening 106. This action separates the deployed suture wire extending through subject portions 110, 112 from the suture wire remaining in wire supply cartridge 30, wire guide 76 and the fixed jaw portion's channel 108.

Then wire cutting actuator 24 is released, allowing biasing spring 69 to return cutting bar 104 to its distal position, and then jaw closing actuator 22 is released, allowing movable jaw portion 98 to move away from fixed jaw portion 96. Suturing instrument 10 may then be removed from subject portions 110, 112, which action will pull wire length 58A from movable jaw portion 98 (Fig. 17I).

The deployed suture wire 58 may then be pressed down flat against subject portions 110, 112, or rounded into a ball, or otherwise operated upon, so as to

reduce the profile of, or reduce the tendency to snag on, the deployed suture wire (Fig. 17J).

It will be appreciated that suturing instrument 10 will have application in a broad range of different suturing operations. More particularly, it will be appreciated that suturing instrument 10 will have application in both "open" and "closed" surgical procedures, with the former including, but not limited to, large entry procedures, relatively shallow procedures, and surface procedures; and with the latter including, but not limited to, surgical procedures where access is gained to an interior structure through the use of a cannula, and surgical procedures where access is gained directly to an internal body cavity without the use of a cannula, e.g., such as a procedure conducted within the colon or the esophagus.

It will also be appreciated that suturing instrument 10 will have application where two portions of tissue must be attached to one another (e.g., where two severed pieces of tissue must be re-attached to one another, or where two separate pieces of tissue must be attached to one another, or where two sections of a

single piece of tissue must be approximated to one another), and where an object must be attached to the patient (e.g., where surgical mesh must be attached to the patient's abdominal wall during hernia repair surgery, etc.).

Among other things, it is believed that suturing instrument 10 will have particular application in the areas of general laparoscopic surgery, general thoracic surgery, cardiac surgery, general intestinal surgery, vascular surgery, skin surgery and plastic surgery.

Looking next at Figs. 18 and 19, it will be seen that where the fixed jaw portion's channel 108 is disposed so as to be substantially aligned with the center of cutting bar 104 (Fig. 18), suture wire 58 will be cut with a relatively flat leading end 58B (Fig. 19). However, it has sometimes been found helpful to provide suture wire 58 with a relatively sharp leading point. Such a leading point can help open the subject for the following portion of the suture wire. In addition, such a leading point can help the suture wire penetrate the subject with a substantially straight path, so that the suture wire

will reliably enter the movable jaw portion's opening 113. To this end, it has been found that moving the fixed jaw portion's channel 108 off-center relative to cutting bar 104 (Fig. 20) will cause the leading end 58B of suture wire 58 to be formed with a relatively sharp tip 58C (Fig. 21).

It is also possible to use suturing instrument 10 to ligate a subject rather than to pass a suture through the subject. For example, suturing instrument 10 might be used to ligate a blood vessel with suture wire 58. In this case, suturing instrument 10 is deployed so that suture wire 58 will pass around the far side of the subject, rather than through the subject as in the case of the suturing operation of the type described above.

By way of example but not limitation, in a typical ligating operation, movable jaw portion 98 is first opened relative to fixed jaw portion 96. Then suturing instrument 10 is positioned about the subject so that when movable jaw portion 98 is thereafter closed toward fixed jaw portion 96, the fixed jaw portion's channel 108 and the movable jaw portion's opening 113 will both

lie on the far side of the subject. The movable jaw portion 98 is then closed against the fixed jaw portion 96, and suture wire 58 is passed from fixed jaw portion 96 to movable jaw portion 98, i.e., around the far side of the subject. The movable jaw portion 98 is then opened, and suture wire 58 is layed out as the instrument is stepped back from the subject. Then the movable jaw portion 98 is again closed against the fixed jaw portion 96. The shaft of the instrument is then rotated so as to form, and then close down, the ligating loop. Then cutting bar 104 is activated so as to cut the ligating loop from the remainder of the suture wire still in the tool, the movable jaw member 98 is opened, and the instrument is withdrawn from the surgical site. The deployed suture wire 58 may then be pressed down flat against the subject, or rounded into a ball, or otherwise operated upon, so as to reduce the profile of, or reduce the tendency to snag on, the deployed suture wire. As will be appreciated by a person skilled in the art, where instrument 10 is to be used for ligating purposes, fixed jaw portion 96 and movable jaw portion 98 might be formed with a greater

longitudinal length so as to facilitate passing the suture wire around the far side of the subject. Furthermore, movable jaw member 98 might be formed with a recess, intermediate its jaw linkage pin 100 (Fig. 15) and its opening 113, for accommodating the subject, whereby to prevent compressing the subject when movable jaw member 98 is moved into engagement with fixed jaw member 96.

Suture wire 58 may comprise a wire formed out of a metal or any other suitable material having the required flexibility and stiffness. By way of example but not limitation, suture wire 58 may comprise stainless steel, titanium, tantalum, etc.

If desired, suture wire 58 may also be coated with various active agents. For example, suture wire 58 may be coated with an anti-inflammatory agent, or an anti-coagulant agent, or an antibiotic, or a radioactive agent, etc.

Looking next at Fig. 22, it is also possible to impart ultrasound energy to the wire in order to make tissue penetration easier. More particularly, because of the small cross-sectional area of the wire and the

propensity for the wire to buckle when axially loaded, it is beneficial to be able to advance the wire into tissue with a minimum of load. This can be achieved by appropriately applying ultrasound energy to the wire.

A piezoelectric element 200 is placed at the outside radius of the wire guide path 108 at the right angle bend in the fixed jaw portion 96 just before where the wire enters the tissue. The piezoelectric element 200 vibrates at a position along this bend such that it supports the wire in completing the turn but also imparts a component of displacement in the direction of the tissue. Displacement of this kind at ultrasonic frequencies, in addition to the existing wire driving means, would cause the tip of the wire to penetrate the tissue using less force. In addition to reducing the tendency for outright wire buckling, lowering the wire loads will also allow the wire penetration to proceed in a straighter path.

Looking next at Fig. 23A, it will be seen that, in some circumstances, the suture wire 58 may exit fixed jaw portion 96 with a curvature, due to the fact that suture wire 58 follows a curved channel 108 in fixed

jaw portion 96. In some cases this curvature in the suture wire 58 may be quite modest, so that it may be effectively ignored. However, in other circumstances, this curvature might be large enough to cause the suture wire advancing out of fixed jaw portion 96 to miss the target opening 113 in movable jaw portion 98. In this case the curvature in suture wire 58 can present a significant problem. However, and looking now at Fig. 23B, it has been found that the profile of the cutting bar's opening 106 may be modified so as to provide a deflecting die which will counteract undesirable curvature in the suture wire and return the suture wire to a straight path as the suture wire exits fixed jaw portion 96. Alternatively, the profile of the fixed jaw portion's channel 108 may be modified, adjacent to cutting bar 104, so as to provide a similar deflecting die which will counteract undesirable curvature in the suture wire and return the suture wire to a straight path as the suture wire exits fixed jaw portion 96. Furthermore, and looking now at Fig. 23C, the mouth of the movable jaw portion's opening 113 may

be enlarged to help capture a suture wire deviating from a straight path.

Looking next at Fig. 24, it will be seen that one or more legs 300 may be provided on suturing instrument 10, wherein legs 300 help stabilize the tissue during suturing.

And looking next at Fig. 25, it will be seen that a grasper 400, comprising jaws 405 and 410, may be added to suturing instrument 10 to help stabilize the tissue during suturing.

If desired, the end effector 18 of suturing instrument 10 may be constructed so as to have two movable, opposing jaws, rather than one fixed jaw and one movable jaw as described above.

Also, if desired, shaft rotation motor 60 and thumb buttons 26, 28 may be configured so that depressing one button (e.g., button 26) will cause end effector 18 to rotate in one direction (e.g., clockwise), and depressing the other button (e.g., button 28) will cause end effector 18 to rotate in the opposite direction (e.g., counterclockwise).

Referring to Fig. 26, it will be seen that an alternative embodiment of end effector 18' includes a fixed first portion 500 having therein a channel 502 for retaining wire guide 76, and a smaller diameter channel 504 for supporting the suture wire 58. The end effector passageway 107 houses the cutting bar 104.

As shown in Figs. 27 and 28, the alternative embodiment of end effector 18 further includes a fixed second portion 510 forming, in part, the channel 502 and the passageway 107. The fixed second portion 510 of end effector 18' further includes an internal curved surface 512. The curved surface 512 forms in part the bottom of a recess 514 having a first side wall 516 provided by the fixed first portion 500, a second side wall 518 (Fig. 27) provided by the fixed second portion 510, and an opening 520 disposed in a planar distal end 522 (Fig. 28) of the end effector 18'. The planar distal end 522 is formed by planar distal ends 524 and 526 of the fixed first and second portions 500, 510, respectively.

In operation, the suture wire 58 is advanced through the instrument as described above. In the

above-described alternative embodiment of end effector 18', a distal portion 528 of the channel 504 (Fig. 29) is curved, such that the wire 58, upon emergence from the channel 504, drives distally in a circular fashion so as to enter, for example, tissue T and thereafter turn proximally to pass through tissue T'. The circular motion may be stopped at any time to form a partial circle of wire, as shown in Fig. 33, and, alternatively, may be repeated once more, or multiple times more, until the wire-driving means is stopped. The curved surface 512 serves to receive the wire 58 and deflect the wire back toward the tissue in a circular mode.

The tissue T, T' need not be edge-to-edge, and in many circumstances will be layered one upon the other (Figs. 30-32). In Fig. 30 there is illustrated diagrammatically how a suture loop may be established by passing the suture wire 58 through both layers of tissue T, T' and then back through the layers T', T. The suture wire 58 may be discharged from the instrument 10 in increments of selected length to provide discrete individual loops, or selected numbers

of loops, or "stitches". Free ends 530 of the loop, or loops, may be twisted together. In Fig. 31, there is shown a similar loop of suture wire 58, but in this instance the wire 58 has been passed through tissue layer T and looped inside tissue layer T' and back through layer T and appropriately cut to leave the two exposed ends 530 for twisting together. In Fig. 32, a single loop has been placed similarly to that shown in Fig. 31, but cut such that the free ends thereof 530 remain spaced from each other, to provide essentially an "inverted fastener", the free ends of which are on a side of the combined layers T, T' facing the user. A tool 532 (Fig. 33) may be brought to bear on the suture wire free ends 530 to complete formation of the fastener.

The diameter of the suture wire loops generated depends upon the tensile strength, or hardness, of the wire, the diameter of wire, the curvature of the wire as it ejects from the instrument, the material being penetrated, the curvature of the distal path 528, and the angle A (Fig. 29) of the distal end 522 of the end effector 18'. Suture wire for the formation of such

fasteners preferably is provided with a diameter of about .010 inch, though wire of a diameter of about .003-.015 inch has been found useful in particular applications.

Referring to Fig. 34, it will be seen that the looped wire 58 may be disposed in an artery 540 and serve as a stent 542.

The instrument 10 may further be used to eject wire 58 so as to tack onto a tissue, or the like, for moving and holding the tissue in a position removed from a surgical site. Alternatively, a wire fastened adjacent a deep surgical site may be used as a guide wire for the insertion of other instruments.

In Fig. 35 there is shown a portion of an alternative end effector 18" wherein the fixed first portion 500 is provided with the channel 502 for the wire guide 76, and the smaller channel 504 for the suture wire. The passageway 107 for the cutting bar 104 is provided, as in the embodiment shown in Fig. 26. In the embodiment shown in Fig. 35, the cutting bar 104 carries a flexible blade 550 slidably disposed in a blade channel 552 which intersects the suture wire

channel 504. The wire channel 504 is configured to provide a pronounced looping, or coiling, of the wire as the wire ejects from the instrument 10. The fixed portion 500 of the instrument is provided with a curved surface 512 which acts as a defector, directing the force of the driven suture wire and supporting the wire which is very thin and flexible.

In use, when it is desired to cut the suture wire after ejection of a desired length of wire, the operator manipulates the wire cutting actuator 24 to drive the cutting bar 104, and thereby the blade 550, distally, causing the blade 550 to cut through the wire at the intersection of the suture wire channel 504 and the blade channel 552.

As noted above, one of the parameters determining the diameter of the suture loops is the curvature of the wire as it ejects from the instrument. In the embodiment shown in Fig. 35, a pronounced curvature has been selected. It will be apparent that such curvature is a matter of choice in view of the task at hand. Another parameter determining the diameter of the suture loops is the angle A of the distal end 522 of

the effector 18". In a modified embodiment (not shown) of the embodiments of Figs. 28 and 35, the end effector 18', 18" may be pivotally mounted on the instrument so as to accommodate selected angular positioning of the planar distal end 522 relative to the axis of the instrument.

In Fig. 36 there is shown another alternative embodiment of end effector 18''' in which the cutting bar 104' is rotatable, rather than movable axially. In this embodiment, the suture wire advances through the channel 504 and through a notch 554 toward the operational site. Upon manipulation of the wire cutting actuator 24, the cutting bar 104' rotates, causing an edge portion 556 of notch 554 to slice through the suture wire 58.

Referring to Fig. 37, it will be seen that in another alternative embodiment of instrument 10, the shaft 16 may comprise first and second shaft portions 16a, 16b, pivotally connected to each other, such that the end effector 18 can be angulated as needed to access difficult to reach areas and/or to provide an optimum angle of approach.

As is shown in Fig. 38, the end effector side walls 516, 518 and planar distal portions 524, 526 may be interrupted by scalloped surfaces 560, 562 for directing a suture coil, funnel-like, into the recess 514. Thus, a suture wire which might otherwise strike a planar surface 524, 526, probably will engage one of the scalloped surfaces 560, 562, and be directed thereby into engagement with the curved surface 512 of the recess 514.

Referring to Figs. 39-41, it will be seen that in another alternative embodiment of end effector 18, the planar distal portions 524, 526 are provided with rounded cut-outs 570, 572. When the planar distal surfaces 524, 526 are pressed against soft, pliable tissue, the tissue typically bulges into the cut-outs 570, 572 and thereby into the recess 514, permitting the suture wire exiting the wire channel 504 to enter the tissue well beneath the surface of the tissue, that is, penetrating more deeply into the tissue. In this embodiment, the cutting bar 104' is movable axially from the position shown in Fig. 39 to the position

shown in Fig. 40 to effect cutting of the suture wire proximate the exit of the wire channel 504.

As shown in Fig. 41, the cutting bar 104' may be provided at its distal end with a curved surface 574 matching in configuration the curved surface 512 of the recess 514. Thus, when the cutting bar 104' is in its retracted position, the cutting bar surface 574 provides a continuation of the recess curved surface 512 and thereby contributes to guiding the suture wire into a coiled condition.

In addition to performing a cutting operation, the cutting bar 104', when axially movable, may also serve the function of tool 532 shown, in Fig. 33, that is, to press the suture wire 58 into a desired configuration, such as bending the wire free ends into the tissue, again, shown in Fig. 33. A combination of rotative and axial movement of the cutting bar 104' can be used to effect wire forming operations after the wire cutting operation.

While the suture wire 58 may be round in cross section, as is typical, it is recognized that other wire cross-sectional configurations lend themselves to

coiling. Accordingly, the suture wire may be provided with an oval or polygonal cross section.

In Figs. 42a-42c, there is shown in operation a still further embodiment of end effector in which there is disposed a wire tip forming die 580 proximate the distal portion 528 of the suture wire channel 504. When the cutting bar 104 is moved distally to cut the wire 58, the cutting bar pushes the cut end 530 of the wire into the die 580 (Fig. 42b) to bend the wire cut end radially inwardly. Even after elastic recoil of the looped wire, the cut end 530 remains directed inwardly of the loop, so as not to snag or tear surrounding tissue or adjacent organs.

In Fig. 43 there is shown an alternative embodiment in which the die 580 is disposed proximally of the distal portion 528 of the wire channel 504. The cutting bar 104 moves proximally to effect cutting of the suture wire 58 and then retracts further, carrying the cut end 530 of the wire 58 proximally on a cutting bar leg 582 into engagement with the die 580. The die 580 bends the wire cut end 530 inwardly of the formed loop. The cutting bar 104 then moves distally

sufficiently to release the wire portion in the die, such that the end effector 18 may be removed from the suture wire 58.

Various factors can affect how the wire element loops in the tissue. These factors include both wire-related factors (e.g., wire tensile strength, wire yield stress, wire size, etc.) and tissue-related factors (e.g., tissue density, tissue elasticity, tissue thickness, tissue stabilization, etc.).

The aforementioned factors are preferably taken into account when forming wire loops in tissue. For example, when forming a loop in intestine, which tends to be a relatively delicate tissue, it is generally preferable to use a relatively "soft" wire (e.g., 120 kpsi, 0.006 inch wire); correspondingly, when forming a loop in the abdominal wall, which tends to be a relatively tough tissue, it is generally preferable to use a relatively "hard" wire (e.g., 250 kpsi, 0.010 inch wire).

Looking next at Figs. 44-48, it will be seen that an alternative embodiment 18A of end effector 18 uses a pair of opposing jaws (e.g., first jaw 602 and second

jaw 604) to form a loop 606 of wire 58. In one preferred form of the invention, both first jaw 602 and second jaw 604 are movable relative to shaft 16 (e.g., by a linkage 608 connected to jaw closing actuator 22), whereby when jaw closing actuator 22 (Fig. 1) is moved toward and away from handle 14 (Fig. 1), opposing jaws 602, 604 will be moved toward and away from one another, respectively. However, it should also be appreciated that, if desired, one of the jaws 602, 604 could be fixed in position relative to shaft 16, in which case "opening and closing of the jaws" would be effected by moving only the other (i.e., the movable) one of the jaws.

Furthermore, if desired, jaws 602, 604 may rotate about the longitudinal axis of the tool.

First jaw 602 is shown in Figs. 44-48 with its cover plate (not shown) removed so as to expose the internal construction of the jaw. In use, this cover plate is, of course, secured in place so as to close off the interior of the jaw. First jaw 602 includes a first channel 610 (Fig. 45) for receiving the distal end of wire guide 76 (shown in phantom in Fig. 45).

First channel 610 terminates in a distal end surface 611 which acts as a stop for the distal end of wire guide 76. First jaw 602 also includes a second, curved channel 612 for receiving wire 58 as the wire emerges from wire guide 76 and for imparting a selected curvature to that wire before the wire passes toward second jaw 604. This selected wire curvature is preferably set so that wire 58 will assume a loop configuration such as the loop 606 shown in Figs. 44-48. Depending on the curvature of the loop 606 which is being formed, and on the thickness of the tissue to be placed between jaws 602 and 604, if desired, first jaw 602 can include a recess 614 (Fig. 46) in its jaw surface 616 for receiving returning portions of loop 606. If desired, recess 614 can act as a sort of deflecting anvil to receive and redirect the wire 58 returning form tissue 622, 624 (see Fig. 48). In such case, recess 614 actually helps to form loop 606. However, in accordance with the present invention, it is not necessary for recess 614 to act as a deflecting anvil for wire 58, since the curvature of loop 606 can be imparted solely by the geometry of curved second

channel 612 if so desired. Indeed, in certain forms of the invention, recess 614 may be omitted entirely, e.g., where the tissue sandwiched between jaws 602, 604 provides sufficient clearance for loop 606 to form in the gap between first jaw 602 and second jaw 604.

First jaw 602 also includes the passageway 107 (Fig. 45) for receiving cutting bar 104. It will, of course, be appreciated that cutting bar passageway 107 intersects wire passageway 612 at the front end of end effector 18A, e.g., as shown at Figs. 44, 47 and 48, so that cutting bar 104 can separate a formed loop 606 from the remainder of wire 58 at the appropriate time.

Second jaw 604 preferably includes a recess 618 (Fig. 45) corresponding to the size and location of the loop 606 formed by first jaw 602. If desired, recess 618 can also act as a sort of deflecting anvil to receive and redirect the wire 58 received from first jaw 602. In such case, recess 618 actually helps to form loop 606. However, in accordance with the present invention, it is not necessary for recess 618 to act as a deflecting anvil for wire 58, since the curvature of loop 606 can be imparted solely by the geometry of

curved second channel 612 if so desired. Indeed, in certain forms of the invention, recess 618 may be omitted entirely, e.g., where the tissue sandwiched between jaws 602, 604 provides sufficient clearance for loop 606 to form in the gap between first jaw 602 and second jaw 604.

Alternatively, if desired, jaw 604 may be bifurcated, with the loop 606 being formed between the two arms of jaw 604.

First jaw 602 and second jaw 604 preferably also include a plurality of serrations 620 (Figs. 44 and 45) to facilitate gripping tissue between the two jaws.

End effector 18A is intended to be used as follows. First, jaws 602 and 604 are opened. Then the tool is manipulated so that the material which is to be looped (e.g., tissue 622 and 624, as shown in Figs. 47 and 48) is placed between the open jaws. Next, the jaws 602, 604 are closed so as to securely grip the material. Then wire 58 is advanced out of first jaw 602 (i.e., by depressing wire advance button 20) so that the wire loops itself through the target material, thereby forming the loop 606 (Fig. 47). Next, cutting

bar 104 is advanced within its passageway 107 so as to engage, and then sever, wire 58, whereby to separate loop 606 from the remainder of wire 58. Finally, jaw 602, 604 are opened and the looped material is released.

It should, of course, be appreciated that the material being looped with loop 606 may comprise materials other than tissue, e.g., loop 606 may be used to attach hernia mesh to an abdominal wall, or to attach a prosthetic valve to a cardiovascular structure, etc.

It should also be appreciated that, after a suture loop 606 has been set into the subject, jaws 602 and 604 (or some other forceps-type tool) may be closed about the deployed suture loop 606 so as to permanently compress loop 606, whereby to reduce the height of loop 606 and tighten fixation of the subject.

Modifications

It will be appreciated by those skilled in the art that numerous modifications and variations may be made

to the above-disclosed embodiments without departing from the spirit and scope of the present invention.